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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/095,536	06/10/1998	JOHN A. KINK	OPHD-03282	9749

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EXAMINER	
MURPHY, JOSEPH F	

ART UNIT	PAPER NUMBER
1646	22

DATE MAILED: 04/09/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/095,536	KINK, JOHN A.	
	Examiner	Art Unit	
	Joseph F Murphy	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 15-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12, 15-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Formal Matters

Claims 13 and 14 were cancelled, claim 7 was amended, and new claims 24-33 were added in Paper No. 20, 1/22/02. Claims 1-12, 15-33 are pending and under consideration.,

Response to Amendment

The rejection of claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,888,511 (Skurkovich et al.) in view of WO 9814209, has been withdrawn based on Applicant's arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3, 7-15, 19-20, 24-30 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,888,511 (Skurkovich et al.).

U.S. Patent No. 5,888,511 discloses methods of treating autoimmune diseases by administration of antibodies to IL-6 in addition to anti-TNF antibodies (column 5, lines 41-50), thus anticipating claims 7-15. Compositions comprising anti-IL-6 antibodies and antibody to TNF are claimed in claim 3, column 30, lines 10-21, thus anticipating claims 1-3 and 19-20. Claims 24 is anticipated because all mammals are at risk for sepsis, and it is unclear what treatment is intended. The claims encompass the administration of anti-TNF antibodies for all

reasons, including the treatment of autoimmune diseases. Claim 30 is anticipated because the '511 patent discloses methods of treatment wherein the composition comprises anti-IFN antibodies (column 5, lines 41-54). The '511 patent discloses methods of treating humans (column 10, lines 19-26), thus claim 26 is anticipated. The '511 patent discloses methods of methods of administration including intravenously, orally and parenterally at column 18, lines 17-30, thus claims 27-29 are anticipated. The '511 patent at column 15, lines 47-49 disclose the production of (polyclonal) antibodies in mice, rabbits and humans, for use in the disclosed methods.

Applicant argues that the '511 patent is only enabled for a composition of TNF and INFgamma antibodies. However, the instant claims as written are composition claims. The composition of antibodies to TNF and IL-6 are clearly disclosed in the '511 patent, as discussed above. Applicant argues that the '511 patent lacks support for the scope and breadth of instant claim 3. However, the '511 patent at column 15, lines 47-49 disclose the production of (polyclonal) antibodies in mice, rabbits and humans.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12, 15-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,888,511 (Skurkovich et al.) in view of U.S. Patent No. 5,585,098 (Coleman et al.).

The disclosure of U.S. Patent No. 5,888,511 has been set forth above. U.S. Patent No. 5,888,511 does not disclose the use on antibodies derived form avian sources. U.S. Patent No. 5,585,098 discloses the use of polyclonal antibodies prepared from chicken eggs to neutralize systemic pathogens in mammals (column 4, lines 30-50). U.S. Patent No. 5,585,098 further discloses the advantages of using polyclonal antibodies derived from chicken eggs, including, *inter alia*, Chicken antibodies do not react with mammalian complement, Fc receptors, protein A or protein G. Yolk antibodies show great acid and heat resistance. Extraction of yolk antibodies can be performed even on a large scale without costly investment. Concentrating the antibody from egg yolk is a relatively straightforward process. The antibody is not harmed by pasteurization. The FDA regards egg antibody as a food rather than a drug and has granted GRAS (generally accepted as safe) status thereto (column 5, line 61 to column 6 line 2).

Given the advantages of using polyclonal antibodies derived from hen's eggs, it would have been obvious to one of skill in the art at the time the invention was made to make and use the compositions of antibodies, and practice the methods disclosed in U.S. Patent No. 5,888,511 derived from hens eggs.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1646
April 1, 2002

DAVID S. ROMEO
PRIMARY EXAMINER